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September 27, 2023

VIA ECF

Chief Judge Renée Marie Bumb
U.S. District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Re: ***Microspherix LLC v. Merck Sharp & Dohme Corp., et al.***, No. 17-CV-03984:
Summary Judgment Concerning “Target Tissue” Claims

Dear Chief Judge Bumb:

Plaintiff Microspherix writes in response to Organon’s September 22 letter seeking summary judgment relating to the “target tissue” limitation. Consistent with Your Honor’s comments last week, Organon’s motion is premised on a misinterpretation and misapplication of the Court’s construction of the term “target tissue.” Properly understood, target tissue is the target for treatment, *i.e.*, the tissue into which the agent is released and absorbed. The ultimate effect resulting from any treatment can either be local or systemic, but that does not affect what the “target tissue” is. Importantly, the Court did ***not*** adopt Organon’s proposed construction that sought to limit “target tissue” to the site of ultimate ***effect*** of a therapeutic agent, and for good reason: Organon’s proposed construction conflicted with the intrinsic evidence in the patents and would have excluded disclosed embodiments (*e.g.*, hormones or vaccines) that have systemic effect.

Organon’s summary judgment motion is premised on re-introducing its rejected construction, and its argument is even more flawed because it erroneously implies that Microspherix’s expert agrees with its flawed position. Microspherix’s expert, Professor Cima, actually explains in detail how the evidence meets the Court’s claim construction. Moreover, there are admissions from Organon’s own experts that support infringement as well. *See, e.g.*, Ex. 1, Seigel Dep. at 188:13–17 (agreeing that “[t]he ***arm*** [is] the area that [is] ***targeted for treatment*** with Nexplanon.”). Where, as here, a motion presents a genuine dispute of fact that turns on competing expert testimony, summary judgment is not appropriate. *See, e.g., Adasa Inc. v. Avery Dennison Corp.*, 55 F.4th 900, 911 (Fed. Cir. 2022); *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1384 (Fed. Cir. 2011).

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Organon Misconstrues The Court's Claim Construction.

As an initial matter, Organon's letter brief seems premised on the mistaken assumption that the Court adopted wholesale Organon's proposed construction for the term "target tissue." The Court did not do so. In fact, the Court correctly declined to adopt the offending aspect of Organon's proposed construction that sought to limit coverage to only those therapeutic agents having local effect. *See, e.g.*, D.I. 103 at 13 (Organon arguing "the invention is directed to treating disease in tissues local to the site of implantation"). While Organon does not explicitly re-argue claim construction via its letter, it covertly does just that. Thus, Microspherix briefly explains again why Organon's proposed construction was and is flawed.

The intrinsic evidence precludes any construction of "target tissue" that restricts the types of therapeutic agents to those acting locally. *First*, the language of the claims that include the "target tissue" term make clear that this term is not intended to limit the types of therapeutic agents that can be used to those having only local effect. The context of "target tissue" is focused on the ***positioning of the implant*** and where it will release an agent: "... a marker component configured to determine the position of the seed in the target tissue...." Ex. 2, '835 patent at claim 1. *Second*, the specification makes clear that site of drug ***effect***—as opposed to the site of release and absorption—is ***not*** limited to the implantation site only, but rather includes any effect on the patient's physiology, whether it be local or systemic. *See, e.g., id.* at 16:1–4 ("the therapeutically active component 14 is a material that can be [] implanted in a target tissue of an animal subject (*e.g.* a mammal such as a human patient) to exert an effect on the animal's physiology"); 16:6 ("[m]yriad different substances can be used" as therapeutic). While sometimes the site of drug release, absorption and effect may be one and the same—*e.g.*, when directly treating ***diseased*** tissue (a type of target tissue)—the specification nowhere says that the effect of therapeutic agents in all embodiments is limited to the target tissue only. To the contrary, the specification discloses many examples of therapeutic agents that have ***systemic*** rather than local-only effect, including "hormones" and "vaccines." *Id.* at 8:31–32. For all these reasons, the Court correctly declined to adopt Organon's flawed construction, and it should not reconsider that ruling now.

Microspherix Has Offered Substantial Evidence To Support Infringement Under The Court's "Target Tissue" Claim Construction.

Organon's letter brief repeats many of the same mischaracterizations it made when it sought leave to file its motion. According to Organon, Microspherix's expert supposedly "admits that the contraceptive agent in Nexplanon ... treats the female reproductive tract, the mammary glands, the hypothalamus, and the pituitary gland." *Compare* Ltr. Br. at 1–2 *with* D.I. 223 at 1. Not true. Dr. Cima identified numerous Organon documents and other evidence—including FDA-approved prescribing information—that "state[] that the particular location in a woman's upper arm is ***the tissue targeted for treatment*** with the Nexplanon implant." Ex. 3, Cima Op. ¶ 65. Dr. Cima explained that the evidence consistently "shows that the Nexplanon Implant should be

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implanted within the target tissue in the arm based on certain landmarks in the anatomy of the arm.” *Id.*; see also *id.* at ¶¶ 66–67, 114–16, 147–49, *et seq.* In other words, Dr. Cima explained how Nexplanon’s drug (etonogestrel) prevents ovulation and provides contraception, and why a “sufficiently vascularized” “*target tissue*” is selected for implantation of Nexplanon *for treatment* or “etonogestrel therapy.” Ex. 4, Cima Reb. ¶ 48. The notion (Ltr. Br. at 2) that “Dr. Cima ignore[d] the word ‘treatment’” or that he failed to identify “the tissue ‘targeted for treatment’” is demonstrably false.

Organon further mischaracterizes the record when it argues that “Dr. Cima attempts to avoid the[] facts and confuse the jury” and “pivoted in his reply report” to opining that “the arm is the ‘target tissue’” for Nexplanon. Ltr. Br. at 2–3. Dr. Cima’s opening and reply reports are consistent, and he has never equivocated in his understanding of the evidence. Rather, responding to the Organon’s rebuttal expert alleging that Dr. Cima “do[es] not talk about ‘treatment’,” Dr. Cima explained why that expert (and Organon’s present motion) was mistaken. Specifically, Dr. Cima opined that etonogestrel’s systemic effect is “met by choosing a target tissue that is sufficiently vascularized so that systemic delivery can be achieved indirectly through the vascular compartment. The subcutaneous space adjacent to skeletal muscle is such a space....” Ex. 4, Cima Reb. ¶ 48.

In addition to Dr. Cima’s opinions, even *Organon’s own experts* made admissions that create genuine issues of disputed fact. For example, Dr. Seigel, Organon’s OB/GYN expert who prescribes Nexplanon, admitted that “[t]he *arm* [is] the area that [is] *targeted for treatment* with Nexplanon.” Ex. 1, Seigel Dep. at 188:13–17. And outside this litigation, Organon’s infringement and invalidity experts’ publications use the term “target tissue” exactly the way the Kaplan patents and Microspherix’s expert do, *i.e.*, to refer to the site of release and absorption and not necessarily the site of effect. Ex. 5 at 9.2.2 (book edited by Organon expert, Dr. Park, that refers to “target tissue” for “transdermal delivery” of systemic drugs, including “vaccines” “for potent immune responses”); Ex. 6 at 1:21–25; 13:44–52 (patent filed in 2000 by Organon expert, Dr. Mathiowitz, where she refers to “targeted tissue” in gastrointestinal tract for absorption and *not* effect, and possible therapeutic agents include systemically acting drugs such as hormones and vaccines). When confronted with the fact that her own prior writings were consistent with *Microspherix’s* position (and thus inconsistent with Organon’s), all Dr. Mathiowitz could do was erroneously suggest that the Court’s construction somehow deviated from the ordinary meaning. See Ex. 7, Mathiowitz Dep. at 197 (“I’m sorry that the Court defined target tissue for this case. I’m not using the Court definition when I use the word ‘target’ in my patent that was filed in March 27, 2000.”).

In short, there is no basis for summary judgment on this issue. Organon’s arguments may be fodder for cross examination, but there is ample evidence from which a jury could find that Nexplanon infringes the “target tissue” claims under the Court’s claim construction. As such, Organon’s motion for summary judgment should be denied. See, *e.g.*, *Adasa*, 55 F.4th at 911; *Crown Packaging*, 635 F.3d at 1384.

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Sincerely,

/s/ Christopher DeCoro

Christopher DeCoro